UNITED STATES DISTRICT COURT WESTERN DISTRICT OF PENNSYLVANIA

SANDIE SNYDER, RENEE FERA, and PAUL BERAN individually and on behalf

of all others similarly situated,

Plaintiffs,

CLASS ACTION COMPLAINT

Civil Action No.

JURY TRIAL DEMANDED

:

KONINKLIJKE PHILIPS N.V., PHILIPS NORTH AMERICA LLC, and PHILIPS

RS NORTH AMERICA LLC,

v.

Defendants.

CLASS ACTION COMPLAINT

Plaintiffs Sandie Snyder, Renee Fera, and Paul Beran, individually and on behalf of all others similarly situated, through undersigned counsel, allege as follows.

I. NATURE OF THE ACTION

1. Defendants Koninklijke Philips N.V., Philips North America LLC, and Philips RS North America LLC (collectively "Philips") manufacture and sell a variety of products that are intended to help people breathe. These include Continuous Positive Airway Pressure ("CPAP") and Bilevel Positive Airway Pressure ("BiPAP") machines, which are commonly used to treat sleep apnea, and ventilators, which treat respiratory failure. In general, all of these devices express air into patients' airways. CPAP and BiPAP machines are intended for daily use, and ventilators are used continuously while needed. Without these devices, some patients may experience severe symptoms, including heart attack, stroke, and death by asphyxiation.

- 2. On June 14, 2021, Philips announced a recall of many of its CPAP/BiPAP machines and its ventilators (the "Recalled Breathing Machines"). Specifically, the Recalled Breathing Machines contain polyester-based polyurethane ("PE-PUR") foam for sound abatement. Philips announced that this foam may break down and be inhaled or ingested. Further, the PE-PUR foam may emit volatile organic compounds ("VOCs") that are carcinogenic and may be inhaled or ingested, or adversely affect organs. Philips announced these hazards could result in "serious injury which can be life-threatening or cause permanent impairment." Rodney Mell, *Philips Recall Letter* 2021, https://www.philips.com/c-dam/b2bhc/master/landing-pages/src/update/documents/philips-recall-letter-2021-05-a-2021-06-a.pdf
- 3. Philips knew about these very substantial and material risks long before the recall. Patients who use the Recalled Breathing Machines complained about black particles in their machines for several years before the recall. Philips, however, did not warn the public or its customers about these hazards until late April 2021 and did not recall the Recalled Breathing Machines until June 14, 2021.
- 4. Patients use the Recalled Breathing Machines every day but, absent this litigation, Philips will not replace any of the affected devices now or in the future. Philips has no concrete timeline for replacing or repairing any of the Recalled Breathing Machines.
- 5. In fact, Philips timed its recall of the Recalled Breathing Machines to coincide with its launch of the next generation of its affected products that purportedly do not suffer from the same PE-PUR foam issues. Thus, the only safe option that Philips offers to its customers—many

¹ These include the following models: E30; DreamStation ASV; DreamStation ST, AVAPS; SystemOne ASV4; C Series ASV, S/T, AVAPs; OmniLab Advanced Plus; SystemOne (Q Series); DreamStation CPAP, Auto CPAP, BiPAP; DreamStation Go CPAP, APAP; Dorma 400, 500 CPAP; REMStar SE Auto CPAP; Trilogy 100 and 200; Garbin Plus, Aeris, LifeVent; A-Series BiPAP Hybrid A30; A-Series BiPAP V30 Auto; A-Series BiPAP A40; and A-Series BiPAP A30.

of whom need the Recalled Breathing Machines to sleep—is to purchase Philips's newer model, thus profiting Philips further.

6. Plaintiffs bring this Class Action Complaint to represent a class of similarly situated persons defined below, who also purchased the defective Recalled Breathing Machines, and to obtain relief for their injuries.

II. PARTIES

A. PLAINTIFFS

- 7. Plaintiff Sandie Snyder resides in Detroit Lakes, Minnesota. In 2018, while living in Arkansas, she purchased a Dreamstation CPAP machine to treat sleep apnea. She would not have purchased the device had she known it was defective. She demands a refund, a replacement device that is non-defective, costs for ongoing medical monitoring, and all other appropriate damages for injuries suffered as a result of the defective device.
- 8. Plaintiff Renee Fera resides in Pittsburgh, Pennsylvania. Ms. Fera has used a CPAP machine since 2005. In or around 2013, she purchased a Remstarpro System One C Flex CPAP machine to treat sleep apnea. She would not have purchased the device had she known it was defective. She demands a refund, a replacement device that is non-defective, costs for ongoing medical monitoring, and all other appropriate damages for injuries suffered as a result of the defective device. Philips never informed Ms. Fera that her CPAP machine is part of the current recall. She called Philips herself and was informed that her device was part of the recall.
- 9. Plaintiff Paul Beran is a resident of Alexandria, Virginia. In 2019, he purchased a DreamStation BiPAP machine to treat sleep apnea. He has been advised that if he does not regularly use his BiPAP machine, he is at risk for cardiac arrest. Philips never informed Mr. Beran that his BiPAP machine is part of the current recall. He demands a refund, a replacement device

that is non-defective, costs for ongoing medical monitoring, and all other appropriate damages for injuries suffered as a result of the defective device.

B. DEFENDANTS

- 10. Koninklijke Philips N.V. is a Dutch multinational company headquartered in Amsterdam, Netherlands, and is the parent company of Philips North America LLC and Philips RS North America LLC.
- 11. Defendant Philips North America LLC is a Delaware company with its principal place of business in Cambridge, Massachusetts.
- 12. Defendant Philips RS North America LLC (formerly Respironics, Inc.) is a Delaware company headquartered in Pittsburgh, Pennsylvania.
- 13. Reference to "Philips," "Defendant," or "Defendants" refers to each and every Defendant individually and collectively.

III. <u>JURISDICTION AND VENUE</u>

- 14. This Court has subject matter jurisdiction over this class action pursuant to 28 U.S.C. § 1332, as amended by the Class Action Fairness Act of 2005, because the matter in controversy exceeds \$5 million, exclusive of interest and costs, and is a class action in which Plaintiffs and some members of the Class are citizens of states different than Defendants. *See* 28 U.S.C. § 1332(d)(2)(A).
- 15. Venue is proper in this District because Philips RS North America LLC is headquartered in this District, each of the Defendants does business in the Western District of Pennsylvania, and because a substantial part of the events or omissions giving rise to the claim occurred in this District.

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IV. FACTUAL ALLEGATIONS

A. <u>CPAP MACHINES, BIPAP MACHINES, AND VENTILATORS TREAT SERIOUS CONDITIONS</u>

- 16. Sleep apnea is a sleeping disorder in which breathing is disturbed temporarily during sleep. Breathing may stop or become very shallow. This may be associated with fatigue, daytime sleepiness, interrupted sleep, or snoring, among other symptoms. Serious cases can lead to hypertension, heart attack, or stroke, among other medical ailments.
- 17. CPAP therapy is a common treatment for sleep apnea. In CPAP therapy, a machine delivers a flow of air through a mask over the nose or mouth, which increases air pressure in the throat so that the airway does not collapse during inhalation. CPAP therapy assists breathing during sleep and can successfully treat sleep apnea.
- 18. Other therapies to treat sleep apnea include BiPAP therapy and Automatic Positive Airway Pressure ("APAP"). BiPAP machines provide two different pressure settings one for inhalation and one for exhalation.
- 19. Patients who use CPAP or BiPAP machines typically use them every day when they sleep. Symptoms may return quickly if therapy is discontinued.
- 20. Respiratory failure is a condition in which a patient has difficulty breathing or getting enough oxygen into the blood. Many underlying conditions can cause respiratory failure, including physical trauma, sepsis, pneumonia, COVID-19, and drug abuse. Respiratory failure can be fatal.
- 21. Mechanical ventilators, usually just called "ventilators," are often used to treat respiratory failure. Ventilators push air into and out of the patient's lungs like a bellows. Ventilators can also be used in other circumstances, such as during surgery when general

anesthesia may interrupt normal breathing. The COVID-19 crisis has led to a significant increase in the demand for ventilators in the United States and worldwide.

B. PHILIPS RECALLED ITS PRODUCTS DUE TO SERIOUS HEALTH HAZARDS FROM THE FOAM THAT IT UTILIZED

- 22. Philips manufactures and sells CPAP machines, BiPAP machines, and ventilators, among other products. According to Philips's 2020 Annual Report, Sleep & Respiratory Care constituted approximately 49% of Philips' total sales in its Connected Care line of business, which in turn accounted for 28% of Philips' overall sales of about €19.535 billion.
- 23. Philips's flagship CPAP/BiPAP machine product family is the DreamStation family, including the original DreamStation, launched in October 2015, and the DreamStation Go (a travel version). Philips sells DreamStation products through its subsidiary Respironics, which Philips acquired in 2008.
- 24. Many of Philips's CPAP and BiPAP machines and ventilators contain PE-PUR foam for sound abatement. Due to the design of the machines, air passes through this foam before it is pumped into the patient's airway.
- 25. On April 13, 2021, Philips announced it was launching the DreamStation 2, a next-generation machine in its DreamStation product family.
 - 26. Less than two weeks later, on April 26, 2021, Philips announced:

Philips has determined from user reports and testing that there are possible risks to users related to the sound abatement foam used in certain of Philips' sleep and respiratory care devices currently in use. The risks include that the foam may degrade under certain circumstances, influenced by factors including use of unapproved cleaning methods, such as ozone*), and certain environmental conditions involving high humidity and temperature. The majority of the affected devices are in the first-generation DreamStation product family. Philips' recently launched next-generation CPAP platform, DreamStation 2, is not affected. Philips is in the process of engaging with the relevant regulatory agencies regarding this matter and initiating appropriate actions to mitigate these possible risks. Given the estimated scope of the intended precautionary actions on the installed base, Philips has taken a provision of EUR 250 million.

27. On June 14, 2021, Philips issued a further statement:

To date, Philips has produced millions of Bi-Level PAP, CPAP and mechanical ventilator devices using the PE-PUR sound abatement foam. Despite a low complaint rate (0.03% in 2020), Philips determined based on testing that there are possible risks to users related to this type of foam. The risks include that the PE-PUR foam may degrade into particles which may enter the device's air pathway and be ingested or inhaled by the user, and the foam may off-gas certain chemicals. The foam degradation may be exacerbated by use of unapproved cleaning methods, such as ozone,** and high heat and high humidity environments may also contribute to foam degradation.

Therefore, Philips has decided to voluntarily issue a recall notification* to inform patients and customers of potential impacts on patient health and clinical use related to this issue, as well as instructions on actions to be taken.

28. Philips stated that "[t]he majority of the affected devices within the advised 5-year service life are in the first-generation DreamStation product family." Philips elaborated:

Based on the latest analysis of potential health risks and out of an abundance of caution, the recall notification* advises patients and customers to take the following actions:

For patients using affected BiLevel PAP and CPAP devices: Discontinue use of your device and work with your physician or Durable Medical Equipment (DME) provider to determine the most appropriate options for continued treatment. To continue use of your device due to lack of alternatives, consult with your physician to determine if the benefit of continuing therapy with your device outweighs the risks identified in the recall notification.*

For patients using affected life-sustaining mechanical ventilator devices: Do not stop or alter your prescribed therapy until you have talked to your physician. Philips recognizes that alternate ventilator options for therapy may not exist or may be severely limited for patients who require a ventilator for life-sustaining therapy, or in cases where therapy disruption is unacceptable. In these situations, and at the discretion of the treating clinical team, the benefit of continued usage of these ventilator devices may outweigh the risks identified in the recall notification.*

Possible health risks

The company continues to monitor reports of potential safety issues as required by medical device regulations and laws in the markets in which it operates. To date, there have been no reports of death as a result of these issues. Philips has received reports of possible patient impact due to foam degradation. The potential risks of particulate exposure include headache, irritation, inflammation, respiratory issues, and possible toxic and carcinogenic effects. The potential risks of chemical

exposure due to off-gassing include headache, irritation, hypersensitivity, nausea/vomiting, and possible toxic and carcinogenic effects. Philips has received no reports regarding patient impact related to chemical emissions.

29. On the same day, Philips provided additional information in an announcement entitled "clinical information for physicians," which explained that the foam breakdown "may lead to patient harm and impact clinical care."

While there have been limited reports of headache, upper airway irritation, cough, chest pressure and sinus infection that may have been associated with the foam, based on lab testing and evaluations, it may be possible that these potential health risks could result in a wide range of potential patient impact, from transient potential injuries, symptoms and complications, as well as possibly serious injury which can be life-threatening or cause permanent impairment, or require medical intervention to preclude permanent impairment.

30. The announcement by Phillips detailed two types of hazards from the PE-PUR foam in the devices. First, the announcement described dangers due to foam degradation exposure:

Potential Hazard: Philips has determined from user reports and lab testing that under certain circumstances the foam may degrade into particles which may enter the device's air pathway and be ingested or inhaled by the user of its Continuous Positive Airway Pressure (CPAP), BiLevel Positive Airway Pressure (BiLevel PAP) and Mechanical Ventilator devices. The foam degradation may be exacerbated by environmental conditions of higher temperatures and humidity in certain regions. Unauthorized cleaning methods such as ozone may accelerate potential degradation.

The absence of visible particles does not mean that foam breakdown has not already begun. Lab analysis of the degraded foam reveals the presence of potentially harmful chemicals including:

- Toluene Diamine
- Toluene Diisocyanate
- Diethylene glycol
- 31. The European Union considers Toluene Diisocyanate "highly toxic" and has concluded that Toluene Diamine "cannot be considered safe for use" even as a hair dye.

- 32. Philips disclosed that it "has received several complaints regarding the presence of black debris/particles within the airpath circuit (extending from the device outlet, humidifier, tubing, and mask)."
- 33. The second hazard is the possibility of volatile organic compounds ("VOCs"), that is, chemical emissions from the PE-PUR foam. Philips explained:

Potential Hazard: Lab testing performed for and by Philips has also identified the presence of VOCs which may be emitted from the sound abatement foam component of affected device(s). VOCs are emitted as gases from the foam included in the CPAP, BiLevel PAP and MV devices and may have short- and long-term adverse health effects.

Standard testing identified two compounds of concern (COC) may be emitted from the foam that are outside of safety thresholds. The compounds identified are the following:

- Dimethyl Diazine
- Phenol, 2,6-bis (1,1-dimethylethyl)-4-(1-methylpropyl)-
- 34. Philips admitted that the risks of these VOCs include that they "may cause irritation and airway inflammation, and this may be particularly important for patients with underlying lung diseases or reduced cardiopulmonary reserve" and may lead to the following symptoms: "headache, dizziness, irritation (eyes, nose, respiratory tract, skin), hypersensitivity, nausea, vomiting, toxic and carcinogenic effects," as well as "adverse effects to other organs such as kidney and liver."
- 35. Although Philips did not disclose these health risks until June 2021, Philips has known about these health risks for a long time. For example, customers complained to Philips about black particles in their machines for several years before the recall, as evidenced by forum posts and statements from those that follow the industry.

C. PHILIPS HAS NOT REPLACED ANY DEVICES AND DOES NOT PLAN TO DO SO

36. Philips' so-called "recall" does not actually provide patients with new CPAP, BiPAP, or ventilator devices. As Philips' June 14, 2021, announcement explains:

Repair and replacement program

Philips is providing the relevant regulatory agencies with required information related to the launch and implementation of the projected correction. The company will replace the current sound abatement foam with a new material and has already begun the preparations, which include obtaining the relevant regulatory clearances. Philips aims to address all affected devices in scope of this correction as expeditiously as possible.

As part of the program, the first-generation DreamStation product families will be modified with a different sound abatement foam and shipped upon receipt of the required regulatory clearances. Philips' recently launched next-generation CPAP platform, DreamStation 2, is not affected by the issue. To support the program, Philips is increasing the production of its DreamStation 2 CPAP devices, that are available in the US and selected countries in Europe.

- 37. Thus, Philips is not currently replacing the foam in the affected devices and may take a year or more to provide replacement foam, during which time its customers, including Plaintiffs, are at risk of harm due to these defective machines.
- 38. At the same time, Philips intends to profit from the so-called recall by selling more of its next generation product, the DreamStation 2. Philips intentionally timed the recall to coincide with the launch of the DreamStation 2.
- 39. Due to the design of the Recalled Breathing Machines, it is prohibitively difficult for patients to remove or replace the PE-PUR foam themselves. There is also a general shortage of available replacement machines.
- 40. Patients need to use their machines every day, or else their symptoms—which can be severe and life-altering—may return.

- 41. As a result, the recall by Philips leaves patients without any safe, free options. Patients may buy Philips' next-generation product or a competitor's product—at full price.
- 42. Pursuant to the statements issued by Philips that are set forth above, Philips has admitted that the Recalled Breathing Machines are defective and unsafe. The Recalled Breathing Machines are effectively worthless and/or have a far lesser value than what customers paid and would not have been purchased by patients if they were informed of the defect at the time of sale.
- 43. Plaintiffs and the Class Members have all suffered economic injuries as a result of their purchase of the Recalled Breathing Machines.

V. <u>CLASS ALLEGATIONS</u>

44. Plaintiffs bring this action individually and as a class action pursuant to Fed. R. Civ. P. 23(a), 23(b)(2) and/or 23(b)(3). Specifically, the Classes that Plaintiffs seek to represent consists of the following:

Nationwide Class: All persons in the United States who have purchased a Recalled Breathing Machine for personal use.

Pennsylvania Class: All persons in Pennsylvania who have purchased a Recalled Breathing Machine for personal use.

Arkansas Class: All persons in Arkansas who have purchased a Recalled Breathing Machine for personal use.

Virginia Class: All persons in Virginia who have purchased a Recalled Breathing Machine for personal use.

- 45. The Nationwide Class, Arkansas Subclass, Pennsylvania Subclass, and Virginia Subclass are collectively referred to herein as the "Class." Excluded from the Class are Defendants and their employees, officers, and directors; and the Judge(s) and any mediator assigned to this case.
 - 46. Plaintiffs reserve the right to redefine the Class prior to class certification.

- 47. The rights of each member of the Class were violated, harmed, and placed at risk in a similar fashion based upon Defendants' uniform actions.
- 48. This action has been brought and may be properly maintained as a class action for the following reasons:
- a. <u>Numerosity</u>: Members of the Class are so numerous that their individual joinder is impracticable. The proposed Nationwide Class contains at least millions of individuals who purchased a Recalled Breathing Machine. The Class is therefore sufficiently numerous to make joinder impracticable, if not impossible. The precise number of Class Members is unknown to Plaintiffs at this time, but the Class Members are readily ascertainable and can be identified by Defendants' records.
- b. Existence and Predominance of Commons Questions of Fact and Law:

 Common questions of law and fact exist as to all members of the Class. These questions predominate over any questions affecting only individual Class Members. These common legal and factual questions include, without limitation:
 - i. Whether Defendants were unjustly enriched by the sale of the Recalled Breathing Machines;
 - ii. Whether Defendants were negligent in selling the Recalled Breathing Machines;
 - iii. Whether Defendants failed to warn consumers regarding the risks of the Recalled Breathing Machines;
 - iv. Whether Defendants' practices constitute unfair or deceptive acts or practices under state consumer protection statutes;
 - v. The appropriate nature of class-wide equitable relief; and
 - vi. The appropriate measurement of restitution and/or measure of damages to Plaintiffs and members of the Class.

These and other questions of law or fact that are common to the members of the Class predominate over any questions affecting only individual members of the Class.

- c. <u>Typicality</u>: Plaintiff's claims are typical of the claims of all members of the Class who purchased the Recalled Breathing Machines for personal use.
- d. <u>Adequacy</u>: Plaintiffs are adequate representatives of the Class because their interests do not conflict with the interests of the Class that they seek to represent; they have retained counsel competent and highly experienced in complex class action litigation, and they intend to prosecute this action vigorously. The interests of the Class will be fairly and adequately protected by Plaintiffs and their counsel.
- e. <u>Superiority</u>: A class action is superior to other available means of fair and efficient adjudication of the claims of Plaintiffs and the Class. The injury suffered by each Class Member is relatively small in comparison to the burden and expense of individual prosecution of the complex and extensive litigation necessitated by Defendants' conduct. It would be virtually impossible for members of the Class to individually and effectively redress the wrongs done to them. Even if the members of the Class could afford such individual litigation, the court system could not. Individualized litigation presents a potential for inconsistent or contradictory judgments. Individualized litigation also increases the delay and expense to all parties, and to the court system, presented by the complex legal and factual issues of the case. By contrast, a class action presents far fewer management difficulties, and provides the benefits of single adjudication, an economy of scale, and comprehensive supervision by a single court.

VI. EQUITABLE TOLLING OF STATUTES OF LIMITATIONS

49. The running of any statute of limitations has been equitably tolled by reason of Defendants' fraudulent concealment and/or omissions of critical safety information. Through its

affirmative misrepresentations and omissions, Philips actively concealed from Plaintiffs and their physicians the true risks associated with the Recalled Breathing Machines.

50. As a result of Defendants' actions, Plaintiffs and the Class Members were unaware, and could not have reasonably known or learned through reasonable diligence, that they had been exposed to the risks and harms set forth and that those risks and harms were the direct and proximate result of Defendants' acts and omissions.

VII. CAUSES OF ACTION

COUNT I

STRICT LIABILITY-FAILURE TO WARN

- 51. Plaintiffs and the Class incorporate by reference all preceding paragraphs.
- 52. Defendants had a duty to warn Plaintiffs and the Class Members regarding the defect and true risks associated with the Recalled Breathing Machines.
- 53. Defendants failed to provide adequate warnings regarding the risks of the PE-PUR foam.
- 54. Defendants had information regarding the true risks but failed to warn Plaintiffs, Class Members, and their physicians to strengthen their warnings.
- 55. Despite Defendants' obligation to unilaterally strengthen the warnings, Philips instead chose to actively conceal this knowledge.
- 56. Plaintiffs and the Class Members would not have purchased, chosen, and/or paid for all or part of the Recalled Breathing Machines if they knew of the defect and the risks of purchasing the product.
- 57. This defect proximately caused Plaintiffs' and Class Members' injuries which include economic injuries as well as multiple physical injuries, including but not limited to

headache, irritation, inflammation, respiratory issues, exposure to materials with toxic and carcinogenic effects, and exposure to get unknown consequences.

58. Plaintiffs and the Class suffered damages in an amount to be determined at trial.

COUNT II

DESIGN DEFECT STRICT LIABILITY

- 59. Plaintiffs and the Class incorporate by reference all preceding paragraphs.
- 60. The design of the Recalled Breathing Machines, including but not limited to design and use of the PE-PUR foam and the placement of the foam within the Recalled Breathing Machines, was defective and unreasonably dangerous, causing degradation and inhalation of the PE-PUR foam, and causing headaches, irritation, inflammation, respiratory issues, and exposure to materials with toxic and carcinogenic effects.
- 61. The design of the Recalled Breathing Machines and the PE-PUR foam rendered the Recalled Breathing Machines not reasonably fit, suitable, or safe for their intended purpose.
- 62. The dangers of the Recalled Breathing Machines outweighed the benefits and rendered the products unreasonably dangerous. Indeed, there are other CPAP and similar machines that do not use a similarly toxic foam that is subject to degradation, inhalation, and ingestion.
- 63. Safer alternative machines were available that did not suffer from the defect as set forth herein and that did not have an unreasonable risk of harm as with the Recalled Breathing Machines and their unsafe PE-PUR foam, for example, machines made by other manufacturers.
- 64. The risk benefit profile of the Recalled Breathing Machines was unreasonable, and the products should have had stronger and clearer warnings or should not have been sold in the market.
 - 65. The Recalled Breathing Machines did not perform as an ordinary consumer would

expect.

66. Plaintiffs and the Class suffered damages in an amount to be determined at trial.

COUNT III

NEGLIGENT FAILURE TO WARN

- 67. Plaintiffs and the Class incorporate by reference all preceding paragraphs.
- 68. Defendants owed Plaintiffs and Class Members a duty of care and to warn of any risks associated with the Recalled Breathing Machines. Defendants knew or should have known of the true risks but failed to warn Plaintiffs, Class Members, and their doctors.
- 69. Defendants' negligent breach of duty caused Plaintiffs and Class Members economic damages and injuries in the form of headaches, irritation, inflammation, respiratory issues, and exposure to materials with toxic and carcinogenic effects.
- 70. Plaintiffs and Class Members would not have purchased, chosen, and/or paid for all or part of the Recalled Breathing Machines if they knew of the defect and the risks associated with purchasing the product.
 - 71. Plaintiffs and the Class suffered damages in an amount to be determined at trial.

COUNT IV

NEGLIGENT DESIGN DEFECT

- 72. Plaintiffs and the Class incorporate by reference all preceding paragraphs.
- 73. Defendants negligently designed the Recalled Breathing Machines. Philips owed Plaintiffs and the Class a duty to design the Recalled Breathing Machines in a reasonable manner. The design of the Recalled Breathing Machines, including but not limited to the design of the PE-PUR foam and the placement of the PE-PUR foam within the Recalled Breathing Machines, was defective and unreasonably dangerous, causing degradation and inhalation of the foam, and

causing headaches, irritation, inflammation, respiratory issues, and exposure to materials with toxic and carcinogenic effects.

- 74. The design of the Recalled Breathing Machines and the PE-PUR foam rendered the Recalled Breathing Machines not reasonably fit, suitable, or safe for their intended purpose.
- 75. The dangers of the Recalled Breathing Machines outweighed the benefits and rendered the products unreasonably dangerous. Indeed, there are CPAP and similar machines that do not use a similarly toxic foam that is subject to degradation, inhalation, and ingestions.
- 76. Safer alternative machines were available that did not have an unreasonable risk of harm as with the Recalled Breathing Machines and their unsafe foam, for example, machines made by other manufacturers.
- 77. The risk benefit profile of the Recalled Breathing Machines was unreasonable, and the products should have had stronger and clearer warnings or should not have been sold in the market.
- 78. The Recalled Breathing Machines did not perform as an ordinary consumer would expect.
 - 79. Plaintiffs and the Class suffered damages in an amount to be determined at trial.

COUNT V

NEGLIGENT RECALL

- 80. Plaintiffs and the Class incorporate by reference all preceding paragraphs.
- 81. In issuing a voluntary recall, Philips assumed duties to Plaintiffs and the Class to exercise reasonable care in issuing and implementing the recall.

- 82. Philips breached its duties by failing to adequately warn Plaintiffs and the Class of the dangers associated with the use of the Recalled Breathing Machines by refusing to promptly repair or replace the Recalled Breathing Machines.
- 83. As a direct result of Defendants' breach of duty, Plaintiffs and the Class have suffered harm in an amount to be determined at trial.

COUNT VI

BREACH OF EXPRESS WARRANTY

- 84. Plaintiffs and the Class incorporate by reference all preceding paragraphs.
- 85. Defendants warranted the Recalled Breathing Machines "shall be free from defects of workmanship and materials and will perform in accordance with the product specifications for a period of two (2) years from the date of sale."
- 86. Defendants breached this express warranty in connection with the sale and distribution of the Recalled Breathing Machines. At the point of sale, the Recalled Breathing Machines while appearing normal contained immediate defects as set forth herein, rendering them unsuitable and unsafe for personal use by humans.
- 87. Had Plaintiffs and the Class known the Recalled Breathing Machines were unsafe for use, they would not have purchased them.
- 88. Defendants have breached their warranty and refused to provide appropriate warranty relief notwithstanding the risks of using the Recalled Breathing Machines. Plaintiffs and the Class reasonably expected, at the time of purchase, that the Recalled Breathing Machines were safe for their ordinary and intended use.
- 89. As a direct and proximate result of Defendants' breach of express warranty, Plaintiffs and the Class have sustained damages in an amount to be determined at trial.

COUNT VII

BREACH OF THE IMPLIED WARRANTY OF MERCHANTABILITY

- 90. Plaintiffs and the Class incorporate by reference all preceding paragraphs.
- 91. By operation of law, Defendants, as manufacturers of the Recalled Breathing Machines and as the providers of a limited warranty for the Recalled Breathing Machines, impliedly warranted to Plaintiffs and the Class that the Recalled Breathing Machines were of merchantable quality and safe for their ordinary and intended use.
- 92. Defendants breached the implied warranty of merchantability in connection with the sale and distribution of the Recalled Breathing Machines. At the point of sale, the Recalled Breathing Machines while appearing normal contained defects as set forth herein rendering them unsuitable and unsafe for personal use by humans.
- 93. Had Plaintiffs and the Class known the Recalled Breathing Machines were unsafe for use, they would not have purchased them.
- 94. Defendants have refused to provide appropriate warranty relief notwithstanding the risks of using the Recalled Breathing Machines. Plaintiffs and the Class reasonably expected, at the time of purchase, that the Recalled Breathing Machines were safe for their ordinary and intended use.
- 95. As a direct and proximate result of Defendants' breach of the implied warranty of merchantability, Plaintiffs and the Class have sustained damages in an amount to be determined at trial.

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COUNT VII

PENNSYLVANIA UNFAIR TRADE PRACTICES AND CONSUMER PROTECTION LAW 73 P.S. §§ 201-1, ET. SEQ.

ON BEHALF OF THE PENNSYLVANIA SUBCLASS

- 96. Plaintiffs incorporate by reference all preceding paragraphs.
- 97. Plaintiff Fera brings this cause of action individually and on behalf of the members of the Pennsylvania Subclass.
- 98. Plaintiff Fera and the Pennsylvania Subclass Members purchased their Recalled Breathing Machines primarily for personal, family, or household purposes within the meaning of 73 P.S. § 201-9.2.
- 99. All of the acts complained of herein were perpetrated by Defendants in the course of trade or commerce within the meaning of 73 P.S. § 201-2(3).
- 100. The Pennsylvania Unfair Trade Practices and Consumer Protection Law ("Pennsylvania CPL") prohibits unfair or deceptive acts or practices, including, "[e]ngaging in any other fraudulent or deceptive conduct which creates a likelihood of confusion or misunderstanding." 73 P.S. § 201-2(4). Defendants engaged in unlawful trade practices, and unfair or deceptive acts or practices that violated Pennsylvania CPL.
- 101. Defendants participated in unfair or deceptive trade practices that violated the Pennsylvania CPL as described below and alleged throughout the Complaint. By concealing the true risks of the Recalled Breathing Machines, Defendants knowingly and intentionally misrepresented and omitted material facts in connection with the sale of the Recalled Breathing Machines. Defendants systematically misrepresented, concealed, suppressed, or omitted material facts relating to the Recalled Breathing Machines in the course of their business.

- 102. Defendants also engaged in unlawful trade practices by employing deception, deceptive acts or practices, fraud, misrepresentations, or concealment, suppression or omission of any material fact with intent that others rely upon such concealment, suppression or omission, in connection with the sale of the Recalled Breathing Machines.
- 103. Defendants' unfair and deceptive acts or practices occurred repeatedly in Defendants' trade or business, were capable of deceiving a substantial portion of the purchasing public, and imposed a serious safety risk on the public.
- 104. Defendants knew that the risks inherent in the Recalled Breathing Machines made them unsuitable for their intended use.
- 105. Defendants knew or should have known that their conduct violated the Pennsylvania CPL.
- 106. Had Plaintiff Fera and the Pennsylvania Subclass Members known the truth about the Recalled Breathing Machines, they would not have purchased them. Plaintiff Fera and the Pennsylvania Subclass Members did not receive the benefit of their bargain as a result of Defendants' misconduct.
- 107. Defendants owed Plaintiff Fera and the Pennsylvania Subclass Members a duty to disclose the truth about the Recalled Breathing Machines because Defendants: (a) possessed exclusive, specific, and superior knowledge of the true risks of the Recalled Breathing Machines; (b) intentionally concealed the foregoing from Plaintiff Fera and the Pennsylvania Subclass Members; and/or (c) made incomplete representations regarding the Recalled Breathing Machines, while purposefully withholding material facts from Plaintiff Fera and the Pennsylvania Subclass Members that contradicted these representations.

- 108. Plaintiff Fera and the Pennsylvania Subclass Members suffered injury in fact to a legally protected interest. As a result of Defendants' conduct, Plaintiff Fera and the Pennsylvania Subclass Members were harmed and suffered actual damages.
- 109. Defendants' violations present a continuing risk to Plaintiff Fera and the Pennsylvania Subclass Members, as well as to the general public. Defendants' unlawful acts and practices complained of herein affect the public interest.
- 110. Defendants are liable to Plaintiff and the Pennsylvania Subclass Members for treble their actual damages or \$100, whichever is greater, and attorneys' fees and costs under 73 P.S. § 201-9.2(a). Plaintiff Fera and the Pennsylvania Subclass Members are also entitled to an award of punitive damages given that Defendants' conduct was malicious, wanton, willful, oppressive, or exhibited a reckless indifference to the rights of others.

COUNT VIII

ARKANSAS DECEPTIVE TRADE PRACTICES ACT ARK. CODE ANN. §§ 4-88-101, ET SEQ.

ON BEHALF OF THE ARKANSAS SUBCLASS

- 111. Plaintiffs incorporate by reference all preceding paragraphs.
- 112. Plaintiff Snyder brings this cause of action individually and on behalf of the members of the Arkansas Subclass
- 113. The Arkansas Deceptive Trade Practices Act prohibits deceptive and unconscionable trade practices, including, among other things, "[k]nowingly making a false representation as to the characteristics, ingredients, uses, benefits, alterations, source, sponsorship, approval, or certification of goods or services or as to whether goods are original or new or of a particular standard, quality, grade, style, or model" or "[e]ngaging in any other unconscionable, false, or deceptive act or practice in business, commerce, or trade." Ark. Code Ann. § 4-88-107.

- 114. The Arkansas Deceptive Trade Practices Act makes it unlawful to engage in "any deception, fraud, or false pretense" or "[t]he concealment, suppression, or omission of any material fact with intent that others rely upon the concealment, suppression, or omission" "[w]hen utilized in connection with the sale or advertisement of any goods." Ark. Code Ann. § 4-88-108.
- 115. Defendants engaged in unlawful, deceptive, and unconscionable trade practices, deception, fraud, or false pretense, and the concealment, suppression, or omission of any material fact with intent that others rely upon that concealment, suppression, or omission, with respect to the sale and advertisement of the Recalled Breathing Machines purchased by Plaintiff Snyder and Arkansas Subclass Members, in violation of Ark. Code Ann. §§ 4-88-101, *et seq.*, including by misrepresenting the true quality of the Recalled Breathing Machines, and concealing the true risks of the Recalled Breathing Machines.
- 116. The above deceptive and unconscionable trade practices or acts by Defendants were conducted in connection with the sale or advertisement of "goods," as defined by Ark. Code Ann. § 4-88-102(4).
- 117. The above unlawful acts or practices by Defendants were immoral, unethical, oppressive, and unscrupulous.
- 118. Defendants' actions were negligent, knowing, and willful, and/or wanton and reckless with respect to the rights of Plaintiff Snyder and the Arkansas Subclass Members.
- 119. Defendants' actions were material to Plaintiff Snyder and Arkansas Subclass Members, who relied on Defendants' representations in that they would not have purchased, chosen, and/or paid for all or part of Recalled Breathing Machines had they known that they were defective.
 - 120. As a direct and proximate result of Defendants' unlawful deceptive and

unconscionable acts or practices, Plaintiff Snyder and Arkansas Class Members suffered an ascertainable loss of money or property, real or personal, as described above, including the past, present and future costs associated with replacement of Recalled Breathing Machines and ongoing medical costs and testing.

121. Plaintiffs Snyder and Arkansas Subclass Members seek relief under Ark. Code Ann. § 4-88-113(f)(1)(A), including, but not limited to injunctive relief, restitution, statutory damages, compensatory damages, punitive damages, and attorneys' fees and costs.

COUNT IX

VIRGINIA CONSUMER PROTECTION ACT VA. CODE ANN. §§ 59.1-196, ET SEQ.

ON BEHALF OF THE VIRGINIA SUBCLASS

- 122. Plaintiffs incorporate by reference all preceding paragraphs.
- 123. Plaintiff Beran brings this cause of action individually and on behalf of the members of the Virginia Subclass.
- 124. Virginia Consumer Protection Act, Va. Code Ann. §§ 59.1-196, et seq. ("VCPA") was enacted to "promote fair and ethical standards of dealings between suppliers and the consuming public."
- 125. The VCPA makes unlawful, among other things, any "deception, fraud, false pretense, false promise, or misrepresentation in connection with a consumer transaction." Va. Code Ann. § 59.1-200.
- 126. Defendants engaged in unfair methods of competition in or affecting commerce, and unfair or deceptive acts or practices in or affecting commerce, with respect to the sale and advertisement of the Recalled Breathing Machines purchased by Plaintiff Beran and Virginia

Subclass Members, in violation of Va. Code Ann. §§ 59.1-196, including by making false representations or concealing the true risks of the Recalled Breathing Machines.

127. The above unfair or deceptive acts or practices by Defendants were conducted as

part of a "consumer transaction" as defined by Va. Code Ann. § 59.1-198.

128. The above unfair or deceptive acts or practices by Defendants were reasonably

calculated to deceive Class Members and other consumers, and made with intent to deceive.

129. The above unfair or deceptive acts or practices by Defendants did in fact deceive

Class Members and other consumers, causing them damage.

130. The above unfair and deceptive practices and acts by Defendants were immoral,

unethical, oppressive, and unscrupulous.

131. Defendants' actions were negligent, knowing, and willful, and/or wanton and

reckless with respect to the rights of Plaintiff Beran and the Virginia Subclass Members.

132. Plaintiff Beran and the Virginia Subclass Members relied on Defendants'

representations in that they would not have purchased, chosen, and/or paid for all or part of the

Recalled Breathing Machines had they known that they were defective.

133. As a direct and proximate result of Defendants' deceptive acts and practices,

Plaintiff Beran and the Virginia Subclass Members suffered an ascertainable loss of money or

property, real or personal, as described above.

134. Plaintiff Beran and the Virginia Subclass Members seek relief under Va. Code Ann.

§§ 59.1-196, et seq., including but not limited to injunctive relief, compensatory damages, statutory

damages, treble damages, civil penalties and attorneys' fees and costs.

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COUNT X

UNJUST ENRICHMENT (In the Alternative)

On Behalf of the Nationwide Class

- 135. Plaintiffs and the Class incorporate by reference all preceding paragraphs.
- 136. Plaintiffs and the Class Members conferred a tangible and material economic benefit upon Defendants by purchasing the Recalled Breathing Machines. Plaintiffs and Class Members would not have purchased, chosen, and/or paid for all or part of the Recalled Breathing Machines had they known the true risks of using the Recalled Breathing Machines. Defendants are not providing a timely repair or replacement for the Recalled Breathing Machines. Under these circumstances, it would be unjust and inequitable for Defendants to retain the economic benefits they received at the expense of Plaintiffs and the Class.
- 137. Failing to require Defendants to provide remuneration under these circumstances would result in Defendants being unjustly enriched at the expense of Plaintiffs and the Class Members, who endure being exposed to the risk of developing serious medical conditions and can no longer use their Recalled Breathing Machines safely.
- 138. Defendants' retention of the benefit conferred upon them by Plaintiffs and the Class would be unjust and inequitable.
 - 139. Plaintiffs and the Class suffered damages in an amount to be determined at trial.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs request, individually and on behalf of the Class, that this Court:

A. Determine that the claims alleged herein may be maintained as a class action under Rule 23(a), (b)(2), and/or (b)(3) of the Federal Rules of Civil Procedure on behalf of the

Nationwide Class and state subclasses defined above, and designate Plaintiffs as the class

representatives, and Plaintiffs' counsel as Class Counsel;

B. Award equitable and injunctive relief, including but not limited to, requiring

Defendants to institute a medical monitoring program for Plaintiffs and Class Members,

restitution, and disgorgement of profits;

C. Award all actual, general, special, incidental, punitive, and consequential

damages to which Plaintiffs and Class Members are entitled;

D. Award pre-judgment and post-judgment interest on such monetary relief;

E. Award reasonable attorneys' fees and costs; and

F. Grant such further and other relief that this Court deems appropriate.

Date: August 3, 2021 By: /s/ Benjamin Sweet

Benjamin J. Sweet

ben@nshmlaw.com

Joel M. Walker

jmwalker@nshmlaw.com

NYE, STIRLING,

HALE& MILLER, LLP

1145 Bower Hill Road, Suite 104

Pittsburgh, PA 15243

Telephone: (412) 857-5350

William Pietragallo, II

wp@pietragallo.com

Peter St. Tienne Wolff

psw@pietragallo.com

PIETRAGALLO GORDON ALFANO

BOSICK & RASPANTI, LLP

One Oxford Centre, 38th Floor

Pittsburgh, PA 15219

Telephone: (412) 263-2000

Facsimile: (412) 263-2001

Counsel for Plaintiffs and the Putative Class

JURY DEMAND

Plaintiffs and the Class demand a trial by jury on all issues so triable.

Date: August 3, 2021 By: /s/ Benjamin Sweet

Benjamin J. Sweet ben@nshmlaw.com Joel M. Walker

jmwalker@nshmlaw.com

NYE, STIRLING,

HALE& MILLER, LLP

1145 Bower Hill Road, Suite 104

Pittsburgh, PA 15243 Telephone: (412) 857-5350

William Pietragallo, II

wp@pietragallo.com

Peter St. Tienne Wolff

psw@pietragallo.com

PIETRAGALLO GORDON ALFANO

BOSICK & RASPANTI, LLP

One Oxford Centre, 38th Floor Pittsburgh, PA 15219

Telephone: (412) 263-2000 Facsimile: (412) 263-2001

Counsel for Plaintiffs and the Putative Class